

List of Subjects**42 CFR Part 417**

Administrative practice and procedure, Grant programs-health, Health care, health facilities, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, health facilities, Health maintenance organizations (HMO), Medicare+Choice, Penalties, Privacy, Provider-sponsored organizations (PSO), Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, HCFA amends 42 CFR chapter IV as set forth below:

PART 417-HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

1. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (2 U.S.C. 300e, 300e-5, 300e-9), and 31 U.S.C. 9701.

2. Revise §417.402(b) to read as follows:

§417.402 Effective date of initial regulations.

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(b) The changes made to section 1876 of the Act by section 4002 of the Balanced Budget Act (BBA) of 1997 are incorporated in section 422 except for 1876 cost contracts. Upon enactment of the BBA (August 5, 1997) no new cost contracts or service area expansions are accepted by HCFA except for current Health Care Prepayment Plans that may convert to 1876 cost contracts. Also, 1876 cost contracts may not be extended or renewed beyond December 31, 2004.

PART 422--MEDICARE+CHOICE PROGRAM

1. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102, 1851 through 1857, 1859, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w-21 through 1395w-27, and 1395hh).

2. Section 422.2 is amended by:

A. Revising the definitions of "Basic benefits," "Benefits," "M+C plan," "Mandatory supplemental benefits," "Optional supplemental benefits," "Religious and fraternal (RFB) society," "RFB plan," and "Service area."

B. Adding the definition of "National coverage determination."

C. Removing the definitions of "Emergency medical condition," "Emergency services," and "Urgently needed services."

§422.2 Definitions.

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Basic benefits means all Medicare-covered benefits (except hospice services) and additional benefits.

Benefits are health care services that are intended to maintain or improve the health status of enrollees, for which the M+C organization incurs a cost or liability under an M+C plan

(not solely an administrative processing cost). Benefits are submitted and approved through the ACR process.

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M+C plan means health benefits coverage offered under a policy or contract by an M+C organization that includes a specific set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the M+C plan (or in individual segments of a service area, under §422.304(b)(2)).

* * * * *

Mandatory supplemental benefits are health services not covered by Medicare that an M+C enrollee must purchase as part of an M+C plan that are paid for in full, directly by (or on behalf of) Medicare enrollees, in the form of premiums or cost-sharing.

* * * * *

National coverage determination (NCD) means a national policy determination regarding the coverage status of a particular service that HCFA makes under section 1862(a)(1) of the Act, and publishes as a **Federal Register** notice or HCFA ruling. (The term does not include coverage changes mandated by statute.)

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Optional supplemental benefits are health services not covered by Medicare that are purchased at the option of the M+C enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost-sharing. These services may be grouped or offered individually.

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Religious and fraternal benefit (RFB) society means an organization that--

(1) Is described in section 501(c)(8) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of that Act; and

(2) Is affiliated with, carries out the tenets of, and shares a religious bond with, a church or convention or association of churches or an affiliated group of churches.

RFB plan means an M+C plan that is offered by an RFB society.

Service area means a geographic area approved by HCFA within which an M+C-eligible individual may enroll in a particular M+C plan offered by an M+C organization. Each M+C plan must be available to all M+C-eligible individuals within the plan's service area. In deciding whether to approve an M+C plan's proposed service area, HCFA considers the following criteria:

(1) Whether the area meets the "county integrity rule" that a service area generally consists of a full county or counties. However, HCFA may approve a service area that includes a portion of a county if it determines that the "partial county" area is necessary, nondiscriminatory, and in the best interests of the beneficiaries.

(2) The extent to which the proposed services area mirrors service areas of existing commercial health care plans or M+C plans offered by the organization.

(3) For M+C coordinated care plans and network M+C MSA plans, whether the contracting provider network meets the access and availability standards set forth in §422.112. Although not all contracting providers must be located within the plan's service area, HCFA must determine that all services covered under the plan are accessible from the service area.

(4) For non-network M+C MSA plans, HCFA may approve single county non-network M+C MSA plans even if the M+C organization's commercial plans have multiple county service areas.

3. In §422.4, revise paragraph (a)(1)(iii) and add a new paragraph (a)(1)(iv), to read as follows:

§422.4 Types of M+C plans.

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|-----|---|---|---|
| (a) | * | * | * |
| (1) | * | * | * |

(iii) Coordinated care plans include plans offered by health maintenance organizations (HMOs), provider-sponsored organizations (PSOs), preferred provider organizations (PPOs) as specified in paragraph (a)(1)(iv) of this section, RFBs, and other network plans (except network MSA plans).

(iv) A PPO plan is a plan that has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; and is offered by an organization that is not licensed or organized under State law as an HMO.

* * * * *

4. Revise §422.8 to read as follows:

§422.8 Evaluation and determination procedures.

(a) *Basis for evaluation and determination.* (1) HCFA evaluates an application for an M+C contract on the basis of information contained in the application itself and any additional information that HCFA obtains through on-site visits, public hearings, and any other appropriate procedures.

(2) If the application is incomplete, HCFA notifies the contract applicant and allows 60 days from the date of the notice for the contract applicant to furnish the missing information.

(3) After evaluating all relevant information, HCFA determines whether the contract applicant's application meets the applicable requirements of §422.6.

(b) *Use of information from a prior contracting period.* If an M+C organization, HMO, competitive medical plan, or health care prepayment plan has failed to comply with the terms of a previous year's contract with HCFA under title XVIII of the Act, or has failed to complete a corrective action plan during the term of the contract, HCFA may deny an application from a contract applicant based on the contract applicant's failure to comply with that prior contract with HCFA even if the contract applicant meets all of the current requirements.

(c) *Notice of determination.* HCFA notifies each applicant that applies for an M+C contract under this part of its determination and the basis for the determination. The determination may be approval, intent to deny, or denial.

(d) *Approval of application.* If HCFA approves the application, it gives written notice to the contract applicant, indicating that it meets the requirements for an M+C contract.

(e) *Intent to deny.* (1) If HCFA finds that the contract applicant does not appear to meet the requirements for an M+C organization and appears to be able to meet those requirements within 60 days, HCFA gives the contract applicant notice of

intent to deny the application for an M+C contract and a summary of the basis for this preliminary finding.

(2) Within 60 days from the date of the notice, the contract applicant may respond in writing to the issues or other matters that were the basis for HCFA's preliminary finding and may revise its application to remedy any defects HCFA identified.

(f) *Denial of application.* If HCFA denies the application, it gives written notice to the contract applicant indicating--

(1) That the contract applicant does not meet the contract requirements under part C of title XVIII of the Act;

(2) The reasons why the contract applicant does not meet the contract requirements; and

(3) The contract applicant's right to request reconsideration in accordance with the procedures specified in subpart N of this part.

(g) *Oversight of continuing compliance.* (1) HCFA oversees an M+C organization's continued compliance with the requirements for an M+C organization.

(2) If an M+C organization no longer meets those requirements, HCFA terminates the contract in accordance with §422.510.

5. Revise §422.10 to read as follows:

§422.10 Cost-sharing in enrollment-related costs (M+C user fee).

(a) *Basis and scope.* This section implements that portion of section 1857 of the Act that pertains to cost-sharing in enrollment-related costs. It sets forth the procedures that HCFA follows to determine the aggregate annual "user fee" to be contributed by M+C organizations and to assess the required user fees for M+C plans offered by M+C organizations.

(b) *Purpose of assessment.* Section 1857(e)(2) of the Act authorizes HCFA to charge and collect from each M+C plan offered by an M+C organization its pro rate share of fees for administering section 1851 of the Act, relating to dissemination of enrollment information; and section 4360 of the Omnibus Budget Reconciliation Act of 1990, relating to the health insurance counseling and assistance program.

(c) *Applicability.* The fee assessment also applies to those demonstrations for which enrollment is effected or coordinated under section 1851 of the Act.

(d) *Collection of fees.* (1) *Timing of collection.* HCFA collects the fees over 9 consecutive months beginning with January of each fiscal year.

(2) *Amount to be collected.* The aggregate amount of fees for a fiscal year is the lesser of--

(i) The estimated costs to be incurred by HCFA in that fiscal year to carry out the activities described in paragraph (b) of this section; or

(ii) For fiscal year 2000, \$100 million and for fiscal year 2001 and each succeeding year, the M+C portion (as defined in paragraph (e) of this section) of \$100 million.

(e) *M+C portion.* In this section, the term "M+C portion" means, for a fiscal year, the ratio, as estimated by the Secretary of the average number of individuals enrolled in M+C plans during the fiscal year to the average number of individuals entitled to benefits under part A, and enrolled under part B, during the fiscal year.

(f) *Assessment methodology.* (1) The amount of the M+C portion of the user fee each M+C organization must pay is assessed as a percentage of the total Medicare payments to each organization. HCFA determines this percentage rate using the following formula:

A times B divided by C where--

A is the total estimated January payments to all organizations subject to the assessment;

B is the 9-month (January through September) assessment period; and

C is the total fiscal year M+C user fee assessment amount determined in accordance with paragraph (d)(2) of this section.

(2) HCFA determines each organization's pro rata share of the annual fee on the basis of the organization's calculated monthly payment amount during the 9 consecutive months beginning with January. HCFA calculates each organization's monthly pro rata share by multiplying the established percentage rate by the total monthly calculated Medicare payment amount to the organization as recorded in HCFA's payment system on the first day of the month.

(3) HCFA deducts the organization's fee from the amount of Federal funds otherwise payable to the organization for that month under the M+C program.

(4) If assessments reach the amount authorized for the year before the end of September, HCFA discontinues assessment.

(5) If there are delays in determining the amount of the annual aggregate fees specified in paragraph (d)(2) of this section, or the fee percentage rate specified in paragraph (f)(2), HCFA may adjust the assessment time period and the fee percentage amount.

6. Revise §422.50(a) to read as follows:

§422.50 Eligibility to elect an M+C plan.

(a) An individual is eligible to elect an M+C plan if he or she--

(1) Is entitled to Medicare under Part A and enrolled in Part B (except that an individual entitled only to Part B and who was enrolled in an HMO or CMP with a risk contract under part 417 of this chapter on December 31, 1998 may continue to be enrolled in the M+C organization as an M+C plan enrollee);

(2) Has not been medically determined to have end-stage renal disease, except that an individual who develops end-stage renal disease while enrolled in an M+C plan or in a health plan offered by the M+C organization is eligible to elect an M+C plan offered by that organization;

(3) Meets either of the following residency requirements:

(i) Resides in the service area of the M+C plan.

(ii) Resides outside of the service area of the M+C plan and is enrolled in a health plan offered by the M+C organization during the month immediately preceding the month in which the individual is entitled to both Medicare Part A and Part B, provided that an M+C organization chooses to offer this option and that HCFA determines that all applicable M+C access requirements of §422.112 are met for that individual through the M+C plan's established provider network. The M+C organization must furnish the same benefits to these enrollees as to enrollees who reside in the service area;

(4) Has been a member of an Employer Group Health Plan (EGHP) that includes the elected M+C plan, even if the individual lives outside of the M+C plan service area, provided that an M+C organization chooses to offer this option and that HCFA determines that all applicable M+C access requirements at §422.12 are met for that individual through the M+C plan's established provider network. The M+C organization must furnish the same benefits to all enrollees, regardless of whether they reside in the service area;

(5) Completes and signs an election form and gives information required for enrollment; and

(6) Agrees to abide by the rules of the M+C organization after they are disclosed to him or her in connection with the election process.

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7. In §422.54, the heading of paragraph (b) and paragraphs (c)(2), (d)(1), and (d)(3) are revised to read as follows:

§422.54 Continuation of enrollment.

* * * * *

(b) *Basic rule.* * * *

(c) * * *

(2) An enrollee who moves out of the service area into the geographic area designated as the continuation area has the

choice of continuing enrollment or disenrolling from the plan. The enrollee must make the choice of continuing enrollment in a manner specified by HCFA. If no choice is made, the enrollee must be disenrolled from the plan.

* * * * *

(d) * * *

(1) *Continuation of enrollment benefits.* The M+C organization must, at a minimum, provide or arrange for the Medicare-covered benefits as described in §422.101(a).

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(3) *Reasonable cost-sharing.* For services furnished in the continuation area, an enrollee's cost-sharing liability is limited to the cost-sharing amounts required in the M+C plan's service area (in which the enrollee no longer resides).

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8. Section §422.60 is amended by:

A. Revising paragraph (b)(1).

B. Adding paragraph (b)(3).

C. Revising paragraphs (e)(6), (f)(1), and (f)(3).

§422.60 Election process.

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(b) *Capacity to accept new enrollees.* (1) M+C organizations may submit information on enrollment capacity of plans they offer by July 1 of each year as provided by §422.306(a)(1).

* * * * *

(3) HCFA considers enrollment limit requests for an M+C plan service area, other than those submitted with the adjusted community rate proposal, or for a portion of the plan service area, only if the health and safety of beneficiaries is at risk, such as if the provider network is not available to serve the enrollees in all or a portion of the service area.

* * * * *

(e) * * *

(6) Upon receipt of the election form or from the date a vacancy occurs for an individual who was accepted for future enrollment, the M+C organization transmits, within the timeframes specified by HCFA, the information necessary for HCFA to add the beneficiary to its records as an enrollee of the M+C organization.

(f) * * *

(1) In cases in which an M+C organization has both a Medicare contract and a contract with an employer group health plan, and in which the M+C organization arranges for the employer to process election forms for Medicare-entitled group members, who wish to enroll under the Medicare contract, the effective date of the election may be retroactive. Consistent with §422.250(b), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

* * * * *

(3) Upon receipt of the election form from the employer, the M+C organization must submit the enrollment within timeframes specified by HCFA.

9. Section 422.62 is amended by:

A. Removing, in paragraph (a)(3), the phrase "as provide under" and adding in its place the phrase "as provided under".

B. Revising paragraphs (a)(4)(i) and (a)(5)(i).

C. Adding new paragraph (a)(6).

D. Revising paragraph (b)(1).

§422.62 Election of coverage under an M+C plan.

(a) * * *

(4) * * *

(i) Except as provided in paragraphs (a)(4)(ii), (a)(4)(iii), and (a)(6) of this section, an individual who is eligible to elect an M+C plan in 2002 may elect an M+C plan or change his or her election from an M+C plan to original Medicare or to a different M+C plan, or from original Medicare to an M+C plan, but only once during the first 6 months of the year.

* * * * *

(5) * * *

(i) For 2003 and subsequent years, except as provided in paragraphs (a)(5)(ii), (a)(5)(iii), and (a)(6) of this section, an individual who is eligible to elect an M+C plan may elect an

M+C plan, change his or her election from an M+C plan to original Medicare or to a different M+C plan, or from original Medicare to an M+C plan, but only once during the first 3 months of the year.

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(6) *Open enrollment period for institutionalized individuals.* After 2001, an individual who is eligible to elect an M+C plan and who is institutionalized, as defined by HCFA, is not limited (except as provided for in paragraph (d) of this section for M+C MSA plans) in the number of elections or changes he or she may make. Subject to the M+C plan being open to enrollees as provided under §422.60(a)(2), an M+C eligible institutionalized individual may at any time elect an M+C plan or change his or her election from an M+C plan to original Medicare, to a different M+C plan, or from original Medicare to an M+C plan.

(b) * * *

(1) HCFA or the organization has terminated the organization's contract for the plan, discontinued the plan in the area in which the individual resides, or the organization has notified the individual of the impending termination of the plan, or the impending discontinuation of the plan in the area in which the individual resides.

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10. Section 422.64 is revised to read as follows:

§422.64 Information about the M+C program.

Each M+C organization must provide, on an annual basis, and in a format and using standard terminology that may be specified by HCFA, the information necessary to enable HCFA to provide to current and potential beneficiaries the information they need to make informed decisions with respect to the available choices for Medicare coverage.

11. Section §422.66 is amended by:

A. Republishing the heading of paragraph (b) and the introductory text for paragraph (b)(3).

B. Revising paragraphs (b)(3)(i), (d)(1), (d)(3), the introductory text for paragraph (e), and paragraphs (e)(2), and (f).

§422.66 Coordination of enrollment and disenrollment through M+C organizations.

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(b) *Disenrollment--*

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(3) *Responsibilities of the M+C organization.* The M+C organization must--

(i) Submit a disenrollment notice to HCFA within timeframes specified by HCFA;

* * * * *

(d) * * *

(1) *Basic rule.* An M+C plan offered by an M+C organization must accept any individual (regardless of whether the individual has end-stage renal disease) who is enrolled in a health plan offered by the M+C organization during the month immediately preceding the month in which he or she is entitled to both Part A and Part B, and who meets the eligibility requirements at §422.50.

* * * * *

(3) *Effective date of conversion.* If an individual chooses to remain enrolled with the M+C organization as an M+C enrollee, the individual's conversion to an M+C enrollee is effective the month in which he or she is entitled to both Part A and Part B in accordance with the requirements in paragraph (d)(5) of this section.

* * * * *

(e) *Maintenance of enrollment.* An individual who has made an election under this section is considered to have continued to have made that election until either of the following, which ever occurs first:

* * *

(2) The elected M+C plan is discontinued or no longer serves the area in which the individual resides, the organization does

not offer, or the individual does not elect, the option of continuing enrollment, as provided under either §422.54 or §422.74(b)(3)(ii).

(f) *Exception for employer group health plans.* (1) In cases when an M+C organization has both a Medicare contract and a contract with an employer group health plan, and in which the M+C organization arranges for the employer to process election forms for Medicare-entitled group members who wish to disenroll from the Medicare contract, the effective date of the election may be retroactive. Consistent with §422.250(b), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

(2) Upon receipt of the election form from the employer, the M+C organization must submit a disenrollment notice to HCFA within timeframes specified by HCFA.

12. Revise §422.68(c) to read as follows:

§422.68 Effective dates of coverage and change of coverage.

* * * * *

(c) *Open enrollment periods.* For an election, or change in election, made during an open enrollment period as described in §422.62(a)(3) through (a)(6), coverage is effective as of the first day of the first calendar month following the month in which the election is made, except that, if the election or

change in election is made after the 10th day of any calendar month, then the election shall not take effect until the first day of the second calendar month following the date on which the election is made.

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13. Section 422.74 is amended by revising paragraphs (b)(2)(i), (b)(3), (c), (d)(1), the heading of paragraph (d)(3), (d)(4), and (d)(7) to read as follows:

§422.74 Disenrollment by the M+C organization.

* * * * *

(b) * * *

(2) * * *

(i) The individual no longer resides in the M+C plan's service area as specified under paragraph (d)(4) of this section, is no longer eligible under §422.50(a)(3)(ii), and optional continued enrollment has not been offered or elected under §422.54.

* * * * *

(3) *Plan termination or reduction of area where plan is available.* (i) *General rule.* An M+C organization that has its contract for an M+C plan terminated, that terminates an M+C plan, or that discontinues offering the plan in any portion of the area where the plan had previously been available, must disenroll

affected enrollees in accordance with the procedures for disenrollment set forth at paragraph (d)(7) of this section, unless the exception in paragraph (b)(3)(ii) of this section applies.

(ii) *Exception.* When an M+C organization discontinues offering an M+C plan in a portion of its service area, the M+C organization may elect to offer enrollees residing in all or portions of the affected area the option to continue enrollment in an M+C plan offered by the organization, provided that there is no other M+C plan offered in the affected area at the time of the organization's election. The organization may require an enrollee who chooses to continue enrollment to agree to receive the full range of basic benefits (excluding emergency and urgently needed care) exclusively through facilities designated by the organization within the plan service area.

(c) *Notice requirement.* If the disenrollment is for any of the reasons specified in paragraphs (b)(1), (b)(2)(i), or (b)(3) of this section (that is, other than death or loss of entitlement to Part A or Part B) the M+C organization must give the individual a written notice of the disenrollment with an explanation of why the M+C organization is planning to disenroll the individual. Notices for reasons specified in paragraphs (b)(1) through (b)(2)(i) must--

(1) Be mailed to the individual before submission of the disenrollment notice to HCFA; and

(2) Include an explanation of the individual's right to a hearing under the M+C organization's grievance procedures.

(d) * * *

(1) *Monthly basic and supplementary premiums are not paid timely.* An M+C organization may disenroll an individual from the M+C plan for failure to pay any basic and supplementary premiums under the following circumstances:

(i) The M+C organization makes a reasonable effort to collect unpaid premium amounts by sending a written notice of nonpayment to the enrollee within 20 days after the date the delinquent charges were due--

(A) Alerting the individual that the premiums are delinquent;

(B) Providing the individual with an explanation of the disenrollment procedures and any lock-in requirements of the M+C plan; and

(C) Advising that failure to pay the premiums within the 90-day grace period will result in termination of M+C coverage;

(ii) The M+C organization only disenrolls a Medicare enrollee when the organization has not received payment within 90

days after the date it has sent the notice of nonpayment to the enrollee.

(iii) The M+C organization gives the individual a written notice of disenrollment that meets the requirement set forth in paragraph (c) of this section.

(iv) If the enrollee fails to pay the premium for optional supplemental benefits (that is, a package of benefits that an enrollee is not required to accept), but pays the basic premium and any mandatory supplemental premium, the M+C organization has the option to discontinue the optional supplemental benefits and retain the individual as an M+C enrollee.

* * * * *

(3) *Individual commits fraud or permits abuse of enrollment card.****

* * * * *

(4) *Individual no longer resides in the M+C plan's service area.* (i) *Basis for disenrollment.* Unless continuation of enrollment is elected under §422.54, the M+C organization must disenroll an individual if the M+C organization establishes, on the basis of a written statement from the individual or other evidence acceptable to HCFA, that the individual has permanently moved out of a plan's service area. If the individual has not moved from the M+C plan's service area, but has left the plan's

service area for more than 6 months, the M+C organization must disenroll the individual.

(ii) *Special rule.* The M+C organization must disenroll an individual who is enrolled in the M+C plan, under the eligibility requirements at §422.50(a)(3)(ii) or (a)(4), if the organization establishes, on the basis of a written statement from the individual or other evidence acceptable to HCFA, that the individual has permanently moved from the residence in which she or he resided at the time of enrollment in the M+C plan, to an area outside the M+C plan service area (unless continuation of enrollment is elected under §422.54). If the individual has not permanently moved from the residence in which she or he resided at the time of enrollment in the M+C plan, but has left the residence for over 6 months, the M+C organization must disenroll the individual.

(iii) *Notice of disenrollment.* The M+C organization must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

* * * * *

(7) *Plan termination or area reduction.* (i) When an M+C organization has its contract for an M+C plan terminated, terminates an M+C plan, or discontinues offering the plan in any

portion of the area where the plan had previously been available, the M+C organization must give each affected M+C plan enrollee a written notice of the effective date of the plan termination or area reduction and a description of alternatives for obtaining benefits under the M+C program.

(ii) The notice must be sent before the effective date of the plan termination or area reduction, and in the timeframes specified in §422.506(a)(2).

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14. Section 422.80 is amended by:

- A. Republishing the introductory text in paragraph (b)(5).
- B. Revising paragraph (b)(5)(v).
- C. Republishing the introductory text in paragraph (c).
- D. Revising paragraph (c)(4).
- E. Adding new paragraphs (e)(1)(vi), (e)(1)(vii), and (e)(1)(viii).
- F. Revising paragraph (f).

§422.80 Approval of marketing materials and election forms.

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(b) * * *

(5) Examples of marketing materials include, but are not limited to:

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(v) Membership communication materials such as membership rules, subscriber agreements (evidence of coverage), member handbooks and wallet card instructions to enrollees.

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(c) *Guidelines for HCFA review.* In reviewing marketing material or election forms under paragraph (a) of this section, HCFA determines that the marketing materials:

* * * * *

(4) Are not materially inaccurate or misleading or otherwise make material misrepresentations.

* * * * *

(e) * * *

(1) * * *

(vi) Use providers or provider groups to distribute printed information comparing the benefits of different health plans unless the materials have the concurrence of all M+C organizations involved and have received prior approval by HCFA. Physicians or providers may distribute health plan brochures (exclusive of application forms) at a health fair or in their offices. Physicians may discuss, in response to an individual patient's inquiry, the various benefits in different health plans.

(vii) Accept plan applications in provider offices or other places where health care is delivered.

(viii) Employ M+C plan names that suggest that a plan is not available to all Medicare beneficiaries. This prohibition shall not apply to M+C plan names in effect on [Insert date: 30 days after date of publication in the Federal Register].

* * * * *

(f) *Employer group retiree marketing.* M+C organizations may develop marketing materials designed for members of an employer group who are eligible for employer-sponsored benefits through the M+C organization, and furnish these materials only to the group members. While the materials must be submitted for approval under paragraph (a) of this section, HCFA will not review portions of these materials that relate to employer group benefits.

15. Revise §422.100 to read as follows:

§422.100 General requirements.

(a) *Basic rule.* Subject to the conditions and limitations set forth in this subpart, an M+C organization offering an M+C plan must provide enrollees in that plan with coverage of the basic benefits described in paragraph (c) of this section (and, to the extent applicable, the benefits described in §422.102) by furnishing the benefits directly or through arrangements, or by

paying for the benefits. HCFA reviews these benefits subject to the requirements of §422.100(g) and the requirements in subpart G of this part.

(b) *Services of noncontracting providers and suppliers.*

(1) An M+C organization must make timely and reasonable payment to or on behalf of the plan enrollee for the following services obtained from a provider or supplier that does not contract with the M+C organization to provide services covered by the M+C plan:

(i) Ambulance services dispatched through 911 or its local equivalent as provided in §422.113.

(ii) Emergency and urgently needed services as provided in §422.113.

(iii) Maintenance and post-stabilization care services as provided in §422.113.

(iv) Renal dialysis services provided while the enrollee was temporarily outside the plan's service area.

(v) Services for which coverage has been denied by the M+C organization and found (upon appeal under subpart M of this part) to be services the enrollee was entitled to have furnished, or paid for, by the M+C organization.

(2) An M+C plan (other than an M+C MSA plan) offered by an M+C organization satisfies paragraph (a) of this section with

respect to benefits for services furnished by a noncontracting provider if that M+C plan provides payment in an amount the provider would have received under original Medicare (including balance billing permitted under Medicare Part A and Part B).

(c) *Types of benefits.* An M+C plan includes at a minimum basic benefits, and also may include mandatory and optional supplemental benefits.

(1) Basic benefits are all Medicare-covered services, except hospice services, and additional benefits as defined in §422.2 and meeting all requirements in §422.312.

(2) Supplemental benefits, which consist of--

(i) Mandatory supplemental benefits are services not covered by Medicare that an M+C enrollee must purchase as part of an M+C plan that are paid for in full, directly by (or on behalf of) Medicare enrollees, in the form of premiums or cost-sharing.

(ii) Optional supplemental benefits are health services not covered by Medicare that are purchased at the option of the M+C enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost-sharing. These services may be grouped or offered individually.

(d) *Availability and structure of plans.* An M+C organization offering an M+C plan must offer it--

(1) To all Medicare beneficiaries residing in the service area of the M+C plan;

(2) At a uniform premium, with uniform benefits and cost-sharing throughout the plan's service area, or segment of service area as provided in §422.304(b)(2).

(e) *Terms of M+C plans.* Terms of M+C plans described in instructions to beneficiaries, as required by §422.111, will include basic and supplemental benefits and terms of coverage for those benefits.

(f) *Multiple plans in one service area.* An M+C organization may offer more than one M+C plan in the same service area subject to the conditions and limitations set forth in this subpart for each M+C plan.

(g) *HCFA review and approval of M+C benefits.* HCFA reviews and approves M+C benefits using written policy guidelines and requirements in this part, operational policy letters, and other HCFA instructions to ensure that--

(1) Medicare-covered services meet HCFA fee-for-service guidelines;

(2) M+C organizations are not designing benefits to discriminate against beneficiaries; and

(3) Benefit design meets other M+C program requirements.

(h) *Benefits affecting screening mammography, influenza vaccine, and pneumococcal vaccine.* (1) Enrollees of M+C organizations may directly access (through self-referral) screening mammography and influenza vaccine.

(2) M+C organizations may not impose cost-sharing for influenza vaccine and pneumococcal vaccine on their M+C plan enrollees.

(i) *Requirements relating to Medicare conditions of participation.* Basic benefits must be furnished through providers meeting the requirements in §422.204(b)(3).

(j) *Provider networks.* The M+C plans offered by an M+C organization may share a provider network as long as each M+C plan independently meets the access and availability standards described at §422.112, as determined by HCFA.

16. Revise §422.101 to read as follows:

§422.101 Requirements relating to basic benefits.

Except as specified in §422.264 (for entitlement that begins or ends during a hospital stay) and §422.266 (with respect to hospice care), each M+C organization must meet the following requirements:

(a) Provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under

both parts) or by Medicare Part B (if entitled only under Part B) and that are available to beneficiaries residing in the plan's service area. Services may be provided outside of the service area of the plan if the services are accessible and available to enrollees.

(b) Comply with --

(1) HCFA's national coverage determinations;

(2) General coverage guidelines included in original Medicare manuals and instructions unless superseded by operational policy letters or regulations in this part; and

(3) Written coverage decisions of local carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered under the M+C plan.

17. Revise §422.102 to read as follows:

§422.102 Supplemental benefits.

(a) *Mandatory supplemental benefits.* (1) Subject to HCFA's approval, an M+C organization may require Medicare enrollees of an M+C plan other than an MSA plan to accept and pay for services in addition to Medicare-covered services described in §422.101 and additional benefits described in §422.312.

(2) If the M+C organization imposes mandatory supplemental benefits, it must impose them on all Medicare beneficiaries enrolled in the M+C plan.

(3) HCFA approves mandatory supplemental benefits if the benefits are designed in accordance with HCFA's guidelines and requirements as stated in this part and instructions and operational policy letters.

(b) *Optional supplemental benefits.* Except as provided in §422.104 in the case of MSA plans, each M+C organization may offer (for election by the enrollee and without regard to health status) services that are not included in the basic benefits as described in §422.100(c) and any mandatory supplemental benefits described in paragraph (a) of this section. Optional supplemental benefits are purchased at the discretion of the enrollee and must be offered to all Medicare beneficiaries enrolled in the M+C plan.

(c) *Payment for supplemental services.* All supplemental benefits are paid for in full, directly by (or on behalf of) the enrollee of the M+C plan.

(d) *Marketing of supplemental benefits.* M+C organizations may offer enrollees a group of services as one optional supplemental benefit, offer services individually, or offer a combination of groups and individual services.

18. Section 422.105 is amended by:

A. Revising the introductory text for paragraph (a).

B. Revising paragraph (f).

§422.105 Special rules for point of service option.

(a) *General rule.* A POS benefit is an option that an M+C organization may offer in an M+C coordinated care plan or network M+C MSA plan to provide enrollees with additional choice in obtaining specified health care services. The organization may offer a POS option--

* * * * *

(f) *POS-related data.* An M+C organization that offers a POS benefit through an M+C plan must report enrollee utilization data at the plan level by both plan contracting providers (in-network) and by non-contracting providers (out-of-network) including enrollee use of the POS benefit, in the form and manner prescribed by HCFA.

19. Revise §422.106 to read as follows:

§422.106 Coordination of benefits with employer group health plans and Medicaid.

(a) *General rule.* If an M+C organization contracts with an employer group health plan (EGHP) that covers enrollees in an M+C plan, or contracts with a State Medicaid agency to provide Medicaid benefits to individuals who are eligible for both Medicare and Medicaid, and who are enrolled in an M+C plan, the enrollees must be provided the same benefits as all other enrollees in the M+C plan, with the EGHP or Medicaid benefits

supplementing the M+C plan benefits. Jurisdiction regulating benefits under these circumstances is as follows:

(1) All requirements of this part that apply to the M+C program apply to the M+C plan coverage provided to enrollees eligible for benefits under an EGHP or Medicaid contract.

(2) Employer benefits that complement an M+C plan, and the marketing materials associated with the benefits, are not subject to review or approval by HCFA. M+C plan benefits provided to members of the EGHP, and the associated marketing materials, are subject to HCFA review and approval.

(3) Medicaid benefits are not reviewed under this part, but are subject to appropriate HCFA review under the Medicaid program. M+C plan benefits provided to individuals entitled to Medicaid benefits provided by the M+C organization under a contract with the State Medicaid agency are subject to M+C rules and requirements.

(b) *Examples.* Employer/Medicaid benefits, permissible EGHP or Medicaid plan benefits include the following:

(1) Payment of a portion or all of the M+C basic and supplemental premiums.

(2) Payment of a portion or all of other cost-sharing amounts approved for the M+C plan.

(3) Other employer-sponsored benefits that may require additional premium and cost-sharing, or other benefits provided by the organization under a contract with the State Medicaid agency.

20. Section 422.108 is amended by:

A. Republishing the introductory text for paragraph (b).

B. Revising paragraphs (b)(2), (c), the introductory text in paragraph (d), and paragraph (e).

C. Adding a new paragraph (f).

§422.108 Medicare secondary payer (MSP) procedures.

* * * * *

(b) *Responsibilities of the M+C organization.* The M+C organization must, for each M+C plan--

* * * * *

(2) Identify the amounts payable by those payers; and

* * * * *

(c) *Collecting from other entities.* The M+C organization may bill, or authorize a provider to bill, other individuals or entities for covered Medicare services for which Medicare is not the primary payer, as specified in paragraphs (d) and (e) of this section.

(d) *Collecting from other insurers or the enrollee.* If a Medicare enrollee receives from an M+C organization covered

services that are also covered under State or Federal workers' compensation, any no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the M+C organization may bill, or authorize a provider to bill any of the following--

* * * * *

(e) *Collecting from group health plans (GHPs) and large group health plans (LGHPs).* An M+C organization may bill a GHP or LGHP for services it furnishes to a Medicare enrollee who is also covered under the GHP or LGHP and may bill the Medicare enrollee to the extent that he or she has been paid by the GHP or LGHP.

(f) *MSP rules and State laws.* Consistent with §422.402 concerning the Federal preemption of State law, the rules established under this section supersede any State laws, regulations, contract requirements, or other standards that would otherwise apply to M+C plans only to the extent that those State laws are inconsistent with the standards established under this part. A State cannot take away an M+C organization's right under Federal law and the MSP regulations to bill, or to authorize providers and suppliers to bill, for services for which Medicare is not the primary payer. Section 1852(a)(4) of the Social Security Act does not prohibit a State from limiting the amount

of the recovery; thus, State law could modify, but not negate, an M+C organization's rights in this regard.

21. In 422.109, the introductory text for paragraph (b) and paragraph (b)(5) are revised to read as follows:

§422.109 Effect of national coverage determinations (NCDs).

* * * * *

(b) The M+C organization must furnish, arrange or pay for an NCD "significant cost" service before the adjustment of the annual M+C capitation rate. The following rules apply to these services:

* * * * *

(5) Beneficiaries are liable for any applicable coinsurance amounts, but are not responsible for the Part A deductible.

* * * * *

22. Revise §422.110(c) to read as follows:

§422.110 Discrimination against beneficiaries prohibited.

* * * * *

(c) *Additional requirements.* An M+C organization is required to observe the provisions of the Civil Rights Act, Age Discrimination Act, Rehabilitation Act of 1973, and Americans with Disabilities Act (see §422.502(h)).

23. Section 422.111 is amended by:

A. Revising the introductory text in paragraph (a).

B. Revising paragraphs (b)(2)(i), (b)(4), and (b)(5)(i).

C. Republishing the introductory text in paragraph (c) and revising paragraph (c)(1).

D. Revising paragraph (e).

E. Adding new paragraph (f).

§422.111 Disclosure requirements.

(a) *Detailed description.* An M+C organization must disclose the information specified in paragraph (b) of this section--

* * * * *

(b) * * *

(2) * * *

(i) The benefits offered under original Medicare, including the content specified in paragraph (f)(1) of this section;

* * * * *

(4) Out-of-area coverage provided under the plan, including coverage provided to individuals eligible to enroll in the plan under §422.50(a)(3)(ii).

(5) * * *

(i) Explanation of what constitutes an emergency, referencing the definitions of emergency services and emergency medical condition at §422.113;

* * * * *

(c) *Disclosure upon request.* Upon request of an individual eligible to elect an M+C plan, an M+C organization must provide to the individual the following information:

(1) The information required paragraph (f) of this section.

* * * * *

(e) *Changes to provider network.* The M+C organization must make a good faith effort to provide written notice of a termination of a contracted provider at least 30 calendar days before the termination effective date to all enrollees who are patients seen on a regular basis by the provider whose contracted is terminating, irrespective of whether the termination was for cause or without cause. When a contract termination involves a primary care professional, all enrollees who are patients of that primary care professional must be notified.

(f) *Disclosable information--(1) Benefits under original Medicare.*

(i) Covered services.

(ii) Beneficiary cost-sharing, such as deductibles, coinsurance, and copayment amounts.

(iii) Any beneficiary liability for balance billing.

(2) *Enrollment procedures.* Information and instructions on how to exercise election options under this subpart.

(3) *Rights.* A general description of procedural rights (including grievance and appeals procedures) under original Medicare and the M+C program and the right to be protected against discrimination based on factors related to health status in accordance with §422.110.

(4) *Medigap and Medicare Select.* A general description of the benefits, enrollment rights, and requirements applicable to Medicare supplemental policies under section 1882 of the Act, and provisions relating to Medicare Select policies under section 1882(t) of the Act.

(5) *Potential for contract termination.* The fact that an M+C organization may terminate or refuse to renew its contract, or reduce the service area included in its contract, and the effect that any of those actions may have on individuals enrolled in that organization's M+C plan.

(6) *Comparative information.* A list of M+C plans that are or will be available to residents of the service area in the following calendar year, and, for each available plan, information on the aspects described in paragraphs (c)(7) through (c)(11) of this section, presented in a manner that facilitates comparison among the plans.

(7) *Benefits.* (i) Covered services beyond those provided under original Medicare.

(ii) Any beneficiary cost-sharing.

(iii) Any maximum limitations on out-of-pocket expenses.

(iv) In the case of an M+C MSA plan, the amount of the annual MSA deposit and the differences in cost-sharing, enrollee premiums, and balance billing, as compared to M+C plans.

(v) In the case of an M+C private fee-for-service plan, differences in cost-sharing, enrollee premiums, and balance billing, as compared to M+C plans.

(vi) The extent to which an enrollee may obtain benefits through out-of-network health care providers.

(vii) The types of providers that participate in the plan's network and the extent to which an enrollee may select among those providers.

(viii) The coverage of emergency and urgently needed services.

(8) *Premiums.* (i) The M+C monthly basic beneficiary premiums.

(ii) The M+C monthly supplemental beneficiary premium.

(9) *The plan's service area.*

(10) *Quality and performance indicators* for benefits under a plan to the extent they are available as follows (and how they compare with indicators under original Medicare):

(i) Disenrollment rates for Medicare enrollees for the 2 previous years, excluding disenrollment due to death or moving outside the plan's service area, calculated according to HCFA guidelines.

(ii) Medicare enrollee satisfaction.

(iii) Health outcomes.

(iv) Plan-level appeal data.

(v) The recent record of plan compliance with the requirements of this part, as determined by the Secretary.

(vi) Other performance indicators.

(11) *Supplemental benefits.* Whether the plan offers mandatory supplemental benefits or offers optional supplemental benefits and the premiums and other terms and conditions for those benefits.

24. Section 422.112 is amended by:

A. Republishing the introductory text to paragraph (a).

B. Revising paragraphs (a)(2), (a)(3) and (a)(9).

C. Adding new paragraph (a)(10).

D. Removing paragraph (c).

§422.112 Access to services.

(a) *Rules for coordinated care plans and network M+C MSA plans.* An M+C organization that offers an M+C coordinated care plan or network M+C MSA plan may specify the networks of

providers from whom enrollees may obtain services if the M+C organization ensures that all covered services, including additional or supplemental services contracted for by (or on behalf of) the Medicare enrollee, are available and accessible under the plan. To accomplish this, the M+C organization must meet the following requirements:

* * * * *

(2) *PCP panel*. Establish a panel of PCPs from which the enrollee may select a PCP. If an M+C organization requires its enrollees to obtain a referral in most situations before receiving services from a specialist, the M+C organization must either assign a PCP for purposes of making the needed referral or make other arrangements to ensure access to medically necessary specialty care.

(3) *Specialty care*. Provide or arrange for necessary specialty care, and in particular give women enrollees the option of direct access to a women's health specialist within the network for women's routine and preventive health care services provided as basic benefits (as defined in §422.2). The M+C organization arranges for specialty care outside of the plan provider network when network providers are unavailable or inadequate to meet an enrollee's medical needs.

* * * * *

(9) *Cultural considerations.* Ensure that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds.

(10) *Ambulance services, emergency and urgently needed services, and post-stabilization care services coverage.* Provide coverage for ambulance services, emergency and urgently needed services, and post-stabilization care services in accordance with §422.113.

* * * * *

25. Add new §422.113 to read as follows:

§422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services.

(a) *Ambulance services.* The M+C organization is financially responsible for ambulance services, including ambulance services dispatched through 911 or its local equivalent, where other means of transportation would endanger the beneficiary's health.

(b) *Emergency and urgently needed services.* (1) *Definitions.*

(i) *Emergency medical condition* means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an

average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in--

(A) Serious jeopardy to the health of the individual or, in the case of a pregnant woman, the health of the woman or her unborn child;

(B) Serious impairment to bodily functions; or

(C) Serious dysfunction of any bodily organ or part.

(ii) *Emergency services* means covered inpatient and outpatient services that are--

(A) Furnished by a provider qualified to furnish emergency services; and

(B) Needed to evaluate or stabilize an emergency medical condition.

(iii) *Urgently needed services* means covered services that are not emergency services as defined this section, provided when an enrollee is temporarily absent from the M+C plan's service (or, if applicable, continuation) area (or, under unusual and extraordinary circumstances, provided when the enrollee is in the service or continuation area but the organization's provider network is temporarily unavailable or inaccessible) when the services are medically necessary and immediately required--

(A) As a result of an unforeseen illness, injury, or condition; and

(B) It was not reasonable given the circumstances to obtain the services through the organization offering the M+C plan.

(2) *M+C organization financial responsibility.* The M+C organization is financially responsible for emergency and urgently needed services--

(i) Regardless of whether the services are obtained within or outside the M+C organization;

(ii) Regardless of whether there is prior authorization for the services.

(A) Instructions to seek prior authorization for emergency or urgently needed services may not be included in any materials furnished to enrollees (including wallet card instructions), and enrollees must be informed of their right to call 911.

(B) Instruction to seek prior authorization before the enrollee has been stabilized may not be included in any materials furnished to providers (including contracts with providers);

(iii) In accordance with the prudent layperson definition of *emergency medical condition* regardless of final diagnosis;

(iv) For which a plan provider or other M+C organization representative instructs an enrollee to seek emergency services within or outside the plan; and

(v) With a limit on charges to enrollees for emergency services of \$50 or what it would charge the enrollee if he or she

obtained the services through the M+C organization, whichever is less.

(3) *Stabilized condition.* The physician treating the enrollee must decide when the enrollee may be considered stabilized for transfer or discharge, and that decision is binding on the M+C organization.

(c) *Maintenance care and post-stabilization care services* (hereafter together referred to as "post-stabilization care services").

(1) *Definition.* *Post-stabilization care services* means covered services, related to an emergency medical condition, that are provided after an enrollee is stabilized in order to maintain the stabilized condition, or, under the circumstances described in paragraph (c)(2)(iii) of this section, to improve or resolve the enrollee's condition.

(2) *M+C organization financial responsibility.* The M+C organization--

(i) Is financially responsible (consistent with §422.214) for post-stabilization care services obtained within or outside the M+C organization that are pre-approved by a plan provider or other M+C organization representative;

(ii) Is financially responsible for post-stabilization care services obtained within or outside the M+C organization that are

not pre-approved by a plan provider or other M+C organization representative, but administered to maintain the enrollee's stabilized condition within 1 hour of a request to the M+C organization for pre-approval of further post-stabilization care services;

(iii) Is financially responsible for post-stabilization care services obtained within or outside the M+C organization that are not pre-approved by a plan provider or other M+C organization representative, but administered to maintain, improve, or resolve the enrollee's stabilized condition if--

(A) The M+C organization does not respond to a request for pre-approval within 1 hour;

(B) The M+C organization cannot be contacted; or

(C) The M+C organization representative and the treating physician cannot reach an agreement concerning the enrollee's care and a plan physician is not available for consultation. In this situation, the M+C organization must give the treating physician the opportunity to consult with a plan physician and the treating physician may continue with care of the patient until a plan physician is reached or one of the criteria in §422.113(c)(3) is met; and

(iv) Must limit charges to enrollees for post-stabilization care services to an amount no greater than what the organization

would charge the enrollee if he or she had obtained the services through the M+C organization.

(3) *End of M+C organization's financial responsibility.* The M+C organization's financial responsibility for post-stabilization care services it has not pre-approved ends when--

(i) A plan physician with privileges at the treating hospital assumes responsibility for the enrollee's care;

(ii) A plan physician assumes responsibility for the enrollee's care through transfer;

(iii) An M+C organization representative and the treating physician reach an agreement concerning the enrollee's care; or

(iv) The enrollee is discharged.

26. Revise §422.118 to read as follows:

§422.118 Confidentiality and accuracy of enrollee records.

For any medical records or other health and enrollment information it maintains with respect to enrollees, an M+C organization must establish procedures to do the following:

(a) Abide by all Federal and State laws regarding confidentiality and disclosure of medical records, or other health and enrollment information. The M+C organization must safeguard the privacy of any information that identifies a particular enrollee and have procedures that specify--

(1) For what purposes the information will be used within the organization; and

(2) To whom and for what purposes it will disclose the information outside the organization.

(b) Ensure that medical information is released only in accordance with applicable Federal or State law, or pursuant to court orders or subpoenas.

(c) Maintain the records and information in an accurate and timely manner.

(d) Ensure timely access by enrollees to the records and information that pertain to them.

27. Section 422.152 is amended by:

A. Revising the heading and introductory text for paragraph (b).

B. Revising the heading and introductory text for paragraph (e).

C. Revising paragraph (e)(1).

D. Republishing the heading of paragraph (f).

E. Adding new paragraph (f)(3).

§422.152 Quality assessment and performance improvement program.

* * * * *

(b) *Requirements for network M+C MSA plans and M+C coordinated care plans other than PPO plans.* An organization

offering a network M+C MSA plan or M+C coordinated care plan other than a PPO plan must do the following:

* * * * *

(e) *Requirements for M+C PPO plans, non-network MSA plans, and M+C private fee-for-service plans.* An organization offering an M+C plan, non-network MSA plan, or private fee-for-service plan must do the following:

(1) Measure performance under the plan using standard measures required by HCFA and report its performance to HCFA. The standard measures may be specified in uniform data collection and reporting instruments required by HCFA and will relate to--

(i) Clinical areas including effectiveness of care, enrollee perception of care, and use of services; and

(ii) Nonclinical areas including access to and availability of services, appeals and grievances, and organizational characteristics.

* * * * *

(f) *Requirements for all types of plans--*

* * * * *

(3) *Remedial action.* For each plan, the organization must correct all problems that come to its attention through internal surveillance, complaints, or other mechanisms.

28. In §422.154, the introductory text for paragraph (b) is republished, and paragraph (b)(2) is revised to read as follows:

§422.154 External review.

* * * * *

(b) *Terms of the agreement.* The agreement must be consistent with HCFA guidelines and include the following provisions:

* * * * *

(2) Except in the case of complaints about quality, exclude review activities that HCFA determines would duplicate review activities conducted as part of an approved accreditation process or as part of HCFA monitoring.

* * * * *

29. Revise paragraphs (a) and (b) in §422.156 to read as follows:

§422.156 Compliance deemed on the basis of accreditation.

(a) *General rule.* An M+C organization is deemed to meet all of the requirements of any of the areas described in paragraph (b) of this section if--

(1) The M+C organization is fully accredited (and periodically reaccredited) for the standards related to the applicable area under paragraph (b) of this section by a private, national accreditation organization approved by HCFA; and

(2) The accreditation organization used the standards approved by HCFA for the purposes of assessing the M+C organization's compliance with Medicare requirements.

(b) *Deemable requirements.* The requirements relating to the following areas are deemable:

- (1) Quality assurance.
- (2) Antidiscrimination.
- (3) Access to services.
- (4) Confidentiality and accuracy of enrollee records.
- (5) Information on advance directives.
- (6) Provider participation rules.

* * * * *

30. Section 422.157 is amended by republishing the introductory text for paragraph (a) and revising paragraphs (a)(3) and (b)(1) to read as follows:

§422.157 Accreditation organizations.

(a) *Conditions for approval.* HCFA may approve an accreditation organization with respect to a given standard under this part if it meets the following conditions:

* * * * *

- (3) It ensures that:

(i) Any individual associated with it, who is also associated with an entity it accredits, does not influence the accreditation decision concerning that entity.

(ii) The majority of the membership of its governing body is not comprised of managed care organizations or their representatives.

(iii) Its governing body has a broad and balanced representation of interests and acts without bias.

* * * * *

(b) *Notice and comment.* (1) *Proposed notice.* HCFA publishes a notice in the **Federal Register** whenever it is considering granting an accreditation organization's application for approval. The notice--

(i) Announces HCFA's receipt of the accreditation organization's application for approval;

(ii) Describes the criteria HCFA will use in evaluating the application; and

(iii) Provides at least a 30-day comment period.

* * * * *

31. Revise the introductory text §422.158(e) to read as follows:

§422.158 Procedures for approval of accreditation as basis for deeming compliance.

* * * * *

(e) *Notice of determination.* HCFA gives the accreditation organization, within 210 days of receipt of its completed application, a formal notice that--

* * * * *

32. Section 422.202 is amended by:

- A. Revising the introductory text of paragraph (b).
- B. Adding a heading to paragraph (c).
- C. Adding a new paragraph (d)

§422.202 Participation procedures

* * * * *

(b) *Consultation.* The M+C organization must establish a formal mechanism to consult with the physicians who have agreed to provide services under the M+C plan offered by the organization, regarding the organization's medical policy, quality assurance programs and medical management procedures and ensure that the following standards are met:

* * * * *

(c) *Subcontracted groups.* ***

* * * * *

(d) *Suspension or termination of contract.* An M+C organization that operates a coordinated care plan or network MSA

plan providing benefits through contracting providers must meet the following requirements:

(1) *Notice to physician.* An M+C organization that suspends or terminates an agreement under which the physician provides services to M+C plan enrollees must give the affected individual written notice of the following:

(i) The reasons for the action, including, if relevant, the standards and profiling data used to evaluate the physician and the numbers and mix of physicians needed by the M+C organization.

(ii) The affected physician's right to appeal the action and the process and timing for requesting a hearing.

(2) *Composition of hearing panel.* The M+C organization must ensure that the majority of the hearing panel members are peers of the affected physician.

(3) *Notice to licensing or disciplinary bodies.* An M+C organization that suspends or terminates a contract with a physician because of deficiencies in the quality of care must give written notice of that action to licensing or disciplinary bodies or to other appropriate authorities.

(4) *Timeframes.* An M+C organization and a contracting provider must provide at least 60 days written notice to each other before terminating the contract without cause.

33. Revise §422.204 to read as follows:

§422.204 Provider selection and credentialing.

(a) *General rule.* An M+C organization must have written policies and procedures for the selection and evaluation of providers. These policies must conform with the credential and recredentialing requirements set forth in paragraph (b) of this section and with the antidiscrimination provisions set forth in §422.205.

(b) *Basic requirements.* An M+C organization must follow a documented process with respect to providers and suppliers who have signed contracts or participation agreements that--

(1) For providers (other than physicians and other health care professionals) requires determination, and redetermination at specified intervals, that each provider is--

(i) Licensed to operate in the State, and in compliance with any other applicable State or Federal requirements; and

(ii) Reviewed and approved by an accrediting body, or meets the standards established by the organization itself;

(2) For physicians and other health care professionals, including members of physician groups, covers--

(i) Initial credentialing that includes written application, verification of licensure or certification from primary sources, disciplinary status, eligibility for payment under Medicare, and site visits as appropriate. The application must be signed and

dated and include an attestation by the applicant of the correctness and completeness of the application and other information submitted in support of the application;

(ii) Recredentialing at least every 2 years that updates information obtained during initial credentialing and considers performance indicators such as those collected through quality assurance programs, utilization management systems, handling of grievances and appeals, enrollee satisfaction surveys, and other plan activities, and that includes an attestation of the correctness and completeness of the new information; and

(iii) A process for consulting with contracting health care professionals with respect to criteria for credentialing and recredentialing.

(3) Specifies that basic benefits must be provided through, or payments must be made to, providers and suppliers that meet applicable requirements of title XVIII and part A of title XI of the Act. In the case of providers meeting the definition of "provider of services" in section 1861(u) of the Act, basic benefits may only be provided through these providers if they have a provider agreement with HCFA permitting them to provide services under original Medicare.

(4) Ensures compliance with the requirements at §422.752(a)(8) that prohibit employment or contracts with

individuals (or with an entity that employs or contracts with such an individual) excluded from participation under Medicare and with the requirements at §422.220 regarding physicians and practitioners who opt out of Medicare.

34. Add §422.205 to read as follows:

§422.205 Provider antidiscrimination rules.

(a) *General rule.* Consistent with the requirements of this section, the policies and procedures concerning provider selection and credentialing established under §422.204, and with the requirement under §422.100(c) that all Medicare-covered services be available to M+C plan enrollees, an M+C organization may select the practitioners that participate in its plan provider networks. In selecting these practitioners, an M+C organization may not discriminate, in terms of participation, reimbursement, or indemnification, against any health care professional who is acting within the scope of his or her license or certification under State law, solely on the basis of the license or certification. If an M+C organization declines to include a given provider or group of providers in its network, it must furnish written notice to the effected provider(s) of the reason for the decision.

(b) *Construction.* The prohibition in paragraph (a)(1) of this section does not preclude any of the following by the M+C organization:

(1) Refusal to grant participation to health care professionals in excess of the number necessary to meet the needs of the plan's enrollees (except for M+C private-fee-for-service plans, which may not refuse to contract on this basis).

(2) Use of different reimbursement amounts for different specialties or for different practitioners in the same specialty.

(3) Implementation of measures designed to maintain quality and control costs consistent with its responsibilities.

35. In §422.206, the heading for paragraph (b) is republished and paragraph (b)(2) is revised to read as follows:
§422.206 Interference with health care professionals' advice to enrollees prohibited.

* * * * *

(b) *Conscience protection.* * * *

(2) Through appropriate written means, makes available information on these policies as follows:

(i) To HCFA, with its application for a Medicare contract, within 10 days of submitting its ACR proposal or, for policy changes, in accordance with §422.80 (concerning approval of marketing materials and election forms) and with §422.111.

(ii) To prospective enrollees, before or during enrollment.

(iii) With respect to current enrollees, the organization is eligible for the exception provided in paragraph (b)(1) of this section if it provides notice of such change within 90 days after adopting the policy at issue; however, under §422.111(d), notice of such a change must be given in advance.

* * * * *

36. Section 422.208 is amended by:

- A. Republishing the introductory text for paragraph (c).
- B. Revising paragraph (c)(2).
- C. Adding a heading to paragraph (e).

§422.208 Physician incentive plans: requirements and limitations.

* * * * *

(c) *Basic requirements.* Any physician incentive plan operated by an M+C organization must meet the following requirements:

* * * * *

(2) If the physician incentive plan places a physician or physician group at substantial financial risk (as determined under paragraph (d) of this section) for services that the physician or physician group does not furnish itself, the M+C organization must assure that all physicians and physician groups

at substantial financial risk have either aggregate or per-patient stop-loss protection in accordance with paragraph (f) of this section, and conduct periodic surveys in accordance with paragraph (h) of this section.

* * * * *

(e) *Prohibition for private M+C fee-for-service plans.****

* * * * *

37. In §422.214, the heading for paragraph (a) is republished and paragraphs (a)(1) and (b) are revised to read as follows:

§422.214 Special rules for services furnished by noncontract providers.

(a) *Services furnished by non-section 1861(u) providers.*

(1) Any provider (other than a provider of services as defined in section 1861(u) of the Act) that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an M+C coordinated care plan or M+C private fee-for-service plan must accept, as payment in full, the amounts that the provider could collect if the beneficiary were enrolled in original Medicare.

* * * * *

(b) *Services furnished by section 1861(u) providers of service.* Any provider of services as defined in section 1861(u)

of the Act that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an M+C coordinated care plan or M+C private fee-for-service plan must accept as payment in full the amounts (less any payments under §§412.105(g) and 413.86(d)) of this chapter that it could collect if the beneficiary were enrolled in original Medicare. (Section 412.105(g) concerns indirect medical education payment to hospitals for managed care enrollees. Section 413.86(d) concerns calculating payment for direct graduate medical education costs.)

38. In §422.216, paragraphs (a)(4), (b)(2), (c)(2), and the introductory text for paragraph (f) are revised to read as follows:

§422.216 Special rules for M+C private fee-for-service plans.

(a) * * *

(4) *Service furnished by providers of service.* Any provider of services as defined in section 1861(u) of the Act that does not have in effect a contract establishing payment mounts for services furnished to a beneficiary enrolled in an M+C private fee-for-service plan must accept as payment in full the amounts (less any payments under §§412.105(g) and 413.86(d) of this chapter) that it could collect if the beneficiary were enrolled in original Medicare.

(b) * * *

(2) *Noncontract providers.* A noncontract provider may not collect from an enrollee more than the cost-sharing established by the M+C private fee-for-service plan as specified in §422.308(b), unless the provider has opted out of Medicare as described in part 405, subpart D of this chapter.

(c) * * *

(2) *Noncontract providers.* An M+C organization that offers an M+C private fee-for-service plan must monitor the amount collected by noncontract providers to ensure that those amounts do not exceed the amounts permitted to be collected under paragraph (b)(2) of this section, unless the provider has opted out of Medicare as described in part 405, subpart D of this chapter. The M+C organization must develop and document violations specified in instructions and must forward documented cases to HCFA.

* * * * *

(f) *Rules describing deemed contract providers.* Any provider furnishing health services, except for emergency services furnished in a hospital pursuant to §489.24 of this chapter, to an enrollee in an M+C private fee-for-service plan, and who has not previously entered into a contract or agreement to furnish services under the plan, is treated as having a

contract in effect and is subject to the limitations of this section that apply to contract providers if the following conditions are met:

* * * * *

39. Section 422.250 is amended by:

A. In paragraph (a)(1), removing the phrase "in paragraph (a)(2)" and adding in its place the phrase "in paragraphs (a)(2) or (f)".

B. Revising paragraph (a)(2)(i)(B).

C. Adding new paragraph (g).

§ 422.250 General provisions.

(a) * * *

(2) * * *

(i) * * *

(B) HCFA reduces the payment rate for each renal dialysis treatment by the same amount that the Secretary is authorized to reduce the amount of each composite rate payment for each treatment as set forth in section 1881(b)(7) of the Act. These funds are be used to help pay for the ESRD network program in the same manner as similar reductions are used in original Medicare.

* * * * *

(g) *Bonus payments.* (1) HCFA provides bonus payments to the M+C organization(s) that first offers a plan in a previously

unserved county on or after January 1, 2000 and no later than December 31, 2001. The bonus payment amounts equal--

(i) For the first 12 months after a plan is offered in a previously unserved county, 5 percent of the monthly capitation rate otherwise payable under this section; and

(ii) For the subsequent 12 months, 3 percent of the monthly capitation rate otherwise payable under this section.

(2) A previously unserved county is defined as--

(i) A county in which no M+C plan has been offered; or

(ii) A county in which an M+C plan or plans has been offered, but where any M+C organization offering an M+C plan notified HCFA by October 13, 1999, that it will no longer offer plans in the county as of January 1, 2000.

(3) A plan is considered to be offered when--

(i) The M+C organization sponsoring the plan has a contract in effect to serve beneficiaries in the previously unserved area; and

(ii) The M+C plan is open for enrollment.

40. Revise §422.254(b)(2) to read as follows:

§422.254 Calculation and adjustment factors.

* * * * *

(b) * * *

(2) The percentage points that HCFA uses to reduce its estimates are as follows:

- (i) For 1998, 0.8 percentage points.
- (ii) For years 1999 through 2001, 0.5 percentage points.
- (iii) For 2002, 0.3 percentage points.
- (iv) For years after 2002, 0 percentage points.

* * * * *

41. In §422.257, revise paragraph (d) and add paragraph (g) to read as follows:

§422.257 Encounter data.

* * * * *

(d) *Other data requirements.* (1) M+C organizations must submit data that conform to the requirements for equivalent data for Medicare fee-for-service when appropriate, and to all relevant national standards.

(2) The data must be submitted electronically to the appropriate HCFA contractor.

(3) M+C organizations must obtain the encounter data required by HCFA from the provider, supplier, physician, or other practitioner that rendered the services.

(4) M+C organizations may include in their contracts with providers, suppliers, physicians, and other practitioners, provisions that require submission of complete and accurate

encounter data as required by HCFA. These provisions may include financial penalties for failure to submit complete data, or for failure to submit data that conform to the requirements for equivalent data for Medicare fee-for-service.

* * * * *

(g) *Deadlines for submission of encounter data.* Risk adjustment factors for each payment year are based on encounter data submitted for services furnished during the 12 month period ending 6 months before to the payment year (for example, risk adjustment factors for CY 2000 are based on data for services furnished during the period July 1, 1998 through June 30, 1999).

(1) The annual deadline for encounter data submission is September 10 for encounter data reflecting services furnished during the 12 month period ending the prior June 30 (for example, the deadline for submission of data for the period July 1, 1998 through June 30, 1999 is September 10, 1999).

(2) HCFA allows a reconciliation process to account for late data submissions. HCFA continues to accept encounter data submitted after the September 10 deadline until June 30 of the payment year (for example, until June 30, 2000 for data from the period July 1, 1998 through June 30, 1999). After the payment year is completed, HCFA recalculates the risk factors for

affected individuals to determine if adjustments to payments are necessary.

42. Revise §422.300(b)(2) to read as follows:

§422.300 Basis and scope.

* * * * *

(b) * * *

(2) For contracts beginning on a date other than January 1 (according to §422.504(d)), M+C organizations may submit ACRs on a date other than July 1 approved by HCFA.

43. Revise §422.304(b) to read as follows:

§422.304 Rules governing premiums and cost-sharing.

* * * * *

(b) *Uniformity.* (1) *General rule.* The M+C monthly basic beneficiary premium, the M+C monthly supplemental beneficiary premiums, and the M+C monthly MSA premium of an M+C organization may not vary among individuals enrolled in an M+C plan (or segment of the plan as provided under paragraph (b)(2) of this section). In addition, the M+C organization may not vary the level of cost-sharing charged for basic benefits or supplemental benefits (if any), among individuals enrolled in an M+C plan (or segment of the plan as provided under paragraph (b)(2) of this section).

(2) Segmented service area option. An M+C organization may apply the uniformity requirements in paragraph (b)(1) of this section to segments of an M+C plan service area (rather than to the entire service area) as long as any such segment is composed of one or more M+C payment areas, and the information specified under §422.306 is submitted separately, as provided in that section, for each such segment.

* * * * *

44. Revise the introductory text in §422.306(a)(1) to read as follows:

§422.306 Submission of proposed premiums and related information.

(a) *General rule.*

(1) Not later than July 1 of each year, each M+C organization and any organization intending to contract as an M+C organization in the subsequent year must submit to HCFA, in the manner and form prescribed by HCFA, for each M+C plan (or service area segment, under §422.304(b)(2)) it intends to offer in the following year--

* * * * *

45. Section 422.310 is amended by:

A. In the introductory text for paragraph (d), removing the phrase "paragraphs (a)(1) and (a)(2) of this section" and adding

in its place the phrase "paragraphs (d)(1) and (d)(2) of this section".

B. Revising paragraph (c)(3).

§422.310 Adjusted community rate (ACR) approval process.

* * * * *

(c) * * *

(3) *Additional revenues.* The relative cost ratio for total revenues for an M+C plan is determined by comparing the total revenues charged on an accrual basis during the most recently ended calendar year prior to submission of the ACR for Medicare enrollees (including payments from HCFA without any needed offsets or reductions, such as, those required by §422.250(a)(2)(i)(B) for ESRD enrollees) that elected the M+C plan to the total revenues charged for non-Medicare enrollees over the same period. The non-Medicare enrollees included in this computation must be consistent with the non-Medicare enrollees included in the initial rate computation. When the relative cost ratio for total revenues is applied to the total initial rate, the value of additional revenues is the remaining value after removing the value of direct medical costs (as adjusted by paragraph (c)(1) of this section) and the value of Administration (as adjusted by paragraph (c)(2) of this section).

* * * * *

46. In §422.312, the introductory text for paragraph (b) is republished and paragraph (b)(1) is revised to read as follows:

§422.312 Requirement for additional benefits.

* * * * *

(b) *Requirement for additional benefits.* If there is an adjusted excess amount for the plan it offers, the M+C organization must --

(1) Provide additional benefits with an actuarial value (less the actuarial value of any cost-sharing associated with the benefit) which HCFA determines is at least equal to the adjusted excess amount; and

* * * * *

47-50. In §422.352, the introductory text for paragraph (a) is republished and paragraph (a)(1) is revised to read as follows:

§422.352 Basic requirements

(a) *General rule.* An organization is considered a PSO for purposes of an M+C contract if the organization-

(1) Has obtained a waiver of State licensure as provided for under §422.370

* * * * *

51. Section 422.500 is amended by:

A. Revising the definition of "clean claim."

B. Adding definitions for "downstream entity" and "first tier entity."

§422.500 Definitions.

* * * * *

Clean claim means--

(1) A claim that has no defect, impropriety, lack of any required substantiating documentation (consistent with §422.257(d)) or particular circumstance requiring special treatment that prevents timely payment; and

(2) A claim that otherwise conforms to the clean claim requirements for equivalent claims under original Medicare.

Downstream entity means any party that enters into an acceptable written arrangement below the level of the arrangement between an M+C organization (or contract applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

First tier entity means any party that enters into an acceptable written arrangement with an M+C organization or contract applicant to provide administrative services or health care services for a Medicare eligible individual.

* * * * *

52. Section 422.501 is amended by:

A. Republishing the introductory text in paragraphs (b), (b)(3), and (b)(3)(vi).

B. Revising paragraphs (b)(3)(vi)(G) and (b)(5).

C. Removing paragraph (b)(3)(vi)(H).

D. Republishing the introductory text in (d)(2) and (d)(2)(iii).

E. Revising paragraph (d)(2)(iii)(A).

§422.501 General provisions.

* * * * *

(b) Conditions necessary to contract as an M+C organization.

Any entity seeking to contract as an M+C organization must:

* * * * *

(3) Have administrative and management arrangements satisfactory to HCFA, as demonstrated by at least the following:

* * * * *

(vi) A compliance plan that consists of the following:

* * * * *

(G) Procedures for ensuring prompt response to detected offenses and development of corrective action initiatives relating to the organization's M+C contract.

* * * * *

(5) The M+C organization's contract must not have been terminated by HCFA under §422.510 within the past 2 years unless--

(i) During the 6-month period beginning on the date the organization notified HCFA of the intention to terminate the most recent previous contract, there was a change in the statute or regulations that had the effect of increasing M+C payments in the payment area or areas at issue; or

(ii) HCFA has otherwise determined that circumstances warrant special consideration.

* * * * *

(d) * * *

(2) Each contract under this section must provide that HCFA, or any person or organization designated by HCFA has the right to:

* * * * *

(iii) Audit and inspect any books, contracts, and records of the M+C organization that pertain to--

(A) The ability of the organization or its first tier or downstream providers to bear the risk of potential financial losses; or

* * * * *

53. Section 422.502 is amended by:

A. In paragraph (a)(12), removing the phrase "To comply will all requirements" and adding in its place the phrase "To comply with all requirements".

B. Republishing the introductory text for paragraph (g).

C. Revising the introductory text for paragraph (g)(1) and the introductory text for paragraph (g)(3).

D. Revising paragraph (i)(3).

E. Revising paragraph (1).

§422.502 Contract provisions.

* * * * *

(g) *Beneficiary financial protections.* The M+C organization agrees to comply with the following requirements:

(1) Each M+C organization must adopt and maintain arrangements satisfactory to HCFA to protect its enrollees from incurring liability (for example, as a result of an organization's insolvency or other financial difficulties) for payment of any fees that are the legal obligation of the M+C organization. To meet this requirement, the M+C organization must--

* * * * *

(3) In meeting the requirements of this paragraph, other than the provider contract requirements specified in paragraph (g)(1)(i) of this section, the M+C organization may use--

* * * * *

(i) * * *

(3) All contracts or written arrangements between M+C organizations and providers, related entities, contractors, subcontractors, first tier and downstream entities must contain the following:

(i) Enrollee protection provisions that provide, consistent with paragraph (g)(1) of this section, arrangements that prohibit providers from holding an enrollee liable for payment of any fees that are the obligation of the M+C organization.

(ii) Accountability provisions that indicate that--

(A) The M+C organization oversees and is accountable to HCFA for any functions or responsibilities that are described in these standards; and

(B) The M+C organization may only delegate activities or functions to a provider, related entity, contractor, or subcontractor in a manner consistent with requirements set forth at paragraph (i)(4) of this section.

(iii) A provision requiring that any services or other activity performed by a related entity, contractor, subcontractor, or first-tier or downstream entity in accordance with a contract or written agreement are consistent and comply with the M+C organization's contractual obligations.

* * * * *

(1) *Certification of data that determine payment.* As a condition for receiving a monthly payment under subpart F of this part, the M+C organization agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of relevant data that HCFA requests. Such data include specified enrollment information, encounter data, and other information that HCFA may specify.

(1) The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify that each enrollee for whom the organization is requesting payment is validly enrolled in an M+C plan offered by the organization and the information relied upon by HCFA in determining payment (based on best knowledge, information, and belief) is accurate, complete, and truthful.

(2) The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best

knowledge, information, and belief) that the encounter data it submits under §422.257 are accurate, complete, and truthful.

(3) If such encounter data are generated by a related entity, contractor, or subcontractor of an M+C organization, such entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data.

(4) The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information, and belief) that the information in its ACR submission is accurate, complete, and truthful and fully conforms to the requirements in §422.310.

54. In §422.504, revise paragraph (b) and remove paragraph (d) to read as follows:

§422.504 Effective date and term of contract.

* * * * *

(b) *Term of contract.* Each contract is for a period of at least 12 months.

* * * * *

55. Section 422.506 is amended by:

A. Republishing the introductory text of paragraph (a)(2).

B. Revising paragraph (a)(2)(i) and the introductory text of paragraph (a)(3).

C. Removing paragraph (b)(1)(ii).

D. Redesignating paragraphs (b)(1)(iii) and (b)(1)(iv) as (b)(1)(ii) and (b)(1)(iii), respectively.

§422.506 Nonrenewal of contract.

(a) * * *

(2) If an M+C organization does not intend to renew its contract, it must notify --

(i) HCFA in writing, by July 1 of the year in which the contract would end;

* * * * *

(3) HCFA may accept a nonrenewal notice submitted after July 1 if --

* * * * *

56. Section 422.510 is amended by adding paragraph (a)(12) and revising paragraph (c)(1) to read as follows:

§422.510 Termination of contract by HCFA

(a) * * *

(12) The M+C organization substantially fails to comply with the marketing requirements in §422.80.

* * * * *

(c) * * *

(1) *General.* Before terminating a contract for reasons other than the grounds specified in paragraph (a)(5) of this section, HCFA provides the M+C organization with reasonable opportunity to develop and receive HCFA approval of a corrective action plan to correct the deficiencies that are the basis of the proposed termination.

57. Revise §422.514(b)(1) to read as follows:

§422.514 Minimum enrollment requirements.

* * * * *

(b) * * *

(1) For a contract applicant or M+C organization that does not meet the applicable requirement of paragraph (a) of this section at application for an M+C contract or during the first 3 years of the contract, HCFA may waive the minimum enrollment requirement as provided for below. To receive a waiver, a contract applicant or M+C organization must demonstrate to HCFA's satisfaction that it is capable of administering and managing an M+C contract and is able to manage the level of risk required under the contract. Factors that HCFA takes into consideration in making this evaluation include the extent to which--

(i) The contract applicant or M+C organization's management and providers have previous experience in managing and providing health care services under a risk-based payment arrangement to at

least as many individuals as the applicable minimum enrollment for the entity as described in paragraph (a) of this section, or

(ii) The contract applicant or M+C organization has the financial ability to bear financial risk under an M+C contract. In determining whether an organization is capable of bearing risk, HCFA considers factors such as the organization's management experience as described in paragraph (b)(1)(i) of this section and stop-loss insurance that is adequate and acceptable to HCFA; and

(iii) The contract applicant or M+C organization is able to establish a marketing and enrollment process that allows it to meet the applicable enrollment requirement specified in paragraph (a) of this section before completion of the third contract year.

* * * * *

58. Revise §422.520(a)(3) to read as follows:

§422.520 Prompt payment by M+C organization.

* * * * *

(a) * * *

(3) All other claims must be paid or denied within 60 calendar days from the date of the request.

* * * * *

§422.550 [Amended]

59. In §422.550(a)(2), the heading "Unincorporated sole proprietor" is removed and the heading "Asset Sale" is added in its place.

60. In §422.561, the introductory text is republished and the definitions of "Appeal" and "Authorized representative" are revised to read as follows:

§422.561 Definitions.

As used in this subpart, unless the context indicates otherwise --

Appeal means any of the procedures that deal with the review of adverse organization determinations on the health care services the enrollee believes he or she is entitled to receive, including delay in providing, arranging for, or approving the health care services (such that a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for a service, as defined under §422.566(b). These procedures include reconsiderations by the M+C organization, and if necessary, an independent review entity, hearings before ALJs, review by the Departmental Appeals Board (DAB), and judicial review.

Authorized representative means an individual authorized by an enrollee, or under State law, to act on his or her behalf in obtaining an organization determination or in dealing with any of

the levels of the appeal process, subject to the rules described in 20 CFR part 404, subpart R, unless otherwise stated in this subpart.

* * * * *

61. Section 422.562 is amended by republishing the introductory text for paragraphs (a) and (a)(1) and revising paragraph (a)(1)(ii).

§422.562 General provisions.

(a) *Responsibilities of the M+C organization.* (1) An M+C organization, with respect to each M+C plan that it offers, must establish and maintain-

* * * * *

(ii) A procedure for making timely organization determinations;

* * * * *

62. Revise §422.566(b) to read as follows:

§422.566 Organization determinations.

* * * * *

(b) *Actions that are organization determinations.* An organization determination is any determination made by an M+C organization with respect to any of the following:

(1) Payment for temporarily out of the area renal dialysis services, emergency services, post-stabilization care, or urgently needed services.

(2) Payment for any other health services furnished by a provider other than the M+C organization that the enrollee believes--

(i) Are covered under Medicare; or

(ii) If not covered under Medicare, should have been furnished, arranged for, or reimbursed by the M+C organization.

(3) The M+C organization's refusal to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the M+C organization.

(4) Discontinuation of a service if the enrollee believes that continuation of the services is medically necessary.

(5) Failure of the M+C organization to approve, furnish, arrange for, or provide payment for health care services in a timely manner, or to provide the enrollee with timely notice of an adverse determination, such that a delay would adversely affect the health of the enrollee.

* * * * *

63. Section 422.568 is revised to read as follows:

§422.568 Standard timeframes and notice requirements for organization determinations.

(a) *Timeframe for requests for service.* When a party has made a request for a service, the M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination. The M+C organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). When the M+C organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision to grant an extension. The M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(b) *Timeframe for requests for payment.* The M+C organization must process requests for payment according to the "prompt payment" provisions set forth in §422.520.

(c) *Written notification by practitioners.* At each patient encounter with an M+C enrollee, a practitioner must notify the enrollee of his or her right to receive, upon request, a detailed written notice from the M+C organization regarding the enrollee's services, consistent with paragraph (d) of this section. The practitioner's notification must--

(1) Provide the enrollee with the information necessary to contact the M+C organization; and

(2) Comply with any other requirements specified by HCFA.

(d) *Written notice for M+C organization denials.* If an enrollee requests an M+C organization to provide a detailed notice of a practitioner's decision to deny a service in whole or in part, or if an M+C organization decides to deny service or payment in whole or in part, it must give the enrollee written notice of the determination.

(e) *Form and content of the M+C organization notice.* The notice of any denial under paragraph (d) of this section must--

(1) Use approved notice language in a readable and understandable form;

(2) State the specific reasons for the denial;

(3) Inform the enrollee of his or her right to a reconsideration;

(4)(i) For service denials, describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeal process; and

(ii) For payment denials, describe the standard reconsideration process and the rest of the appeal process; and

(5) Comply with any other notice requirements specified by HCFA.

(f) *Effect of failure to provide timely notice.* If the M+C organization fails to provide the enrollee with timely notice of an organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed.

64. Section 422.570 is amended by:

- A. Revising paragraph (a).
- B. Republishing the introductory text for paragraph (d).
- C. Revising the introductory text to paragraph (d)(2) and revising paragraph (d)(2)(iii).
- D. Adding a new paragraph (d)(2)(iv).

§422.570 Expediting certain organization determinations.

(a) *Request for expedited determination.* An enrollee or a physician (regardless of whether the physician is affiliated with the M+C organization) may request that an M+C organization expedite an organization determination involving the issues described in §422.566(b)(3) and (b)(4). (This does not include requests for payment of services already furnished.)

* * * * *

(d) *Actions following denial.* If an M+C organization denies a request for expedited determination, it must take the following actions:

* * * * *

(2) Give the enrollee prompt oral notice of the denial and subsequently deliver, within 3 calendar days, a written letter that--

* * * * *

(iii) Informs the enrollee of the right to resubmit a request for an expedited determination with any physician's support; and

(iv) Provides instructions about the grievance process and its timeframes.

* * * * *

65. In §422.572, revise paragraphs (b), (c), and (d) to read as follows:

§422.572 Timeframes and notice requirements for expedited organization determinations.

* * * * *

(b) *Extensions.* The M+C organization may extend the 72-hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). When the M+C organization extends the deadline, it must notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision to grant an extension. The M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(c) *Confirmation of oral notice.* If the M+C organization first notifies an enrollee of its expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

(d) *How the M+C organization must request information from noncontract providers.* If the M+C organization must receive medical information from noncontract providers, the M+C

organization must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited organization determination. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the M+C organization in meeting the required timeframe. Regardless of whether the M+C organization must request information from noncontract providers, the M+C organization is responsible for meeting the timeframe and notice requirements of this section.

* * * * *

66. Section 422.584 is amended by:

- A. Revising paragraph (a).
- B. Republishing the introductory text to paragraph (d).
- C. Revising paragraph (d)(2).

§422.584 Expediting certain reconsiderations.

(a) *Who may request an expedited reconsideration.* An enrollee or a physician (regardless of whether he or she is affiliated with the M+C organization) may request that an M+C organization expedite a reconsideration of a determination that involves the issues described in §422.566(b)(3) and (b)(4). (This does not include requests for payment of services already furnished.)

* * * * *

(d) *Actions following denial.* If an M+C organization denies a request for expedited reconsideration, it must take the following actions:

* * * * *

(2) Give the enrollee prompt oral notice, and subsequently deliver, within 3 calendar days, a written letter that--

(i) Explains that the M+C organization will process the enrollee's request using the 30-day timeframe for standard reconsiderations;

(ii) Informs the enrollee of the right to file a grievance if he or she disagrees with the organization's decision not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited reconsideration with any physician's support; and

(iv) Provides instructions about the grievance process and its timeframes.

* * * * *

67. Section 422.590 is amended by:

A. Republishing the heading for paragraph (a) and revising paragraph (a)(1).

B. Republishing the heading for paragraph (d) and revising paragraphs (d)(2), (d)(3), and (d)(4).

C. Republishing the heading for paragraph (g) and revising paragraph (g)(2).

§422.590 Timeframes and responsibility for reconsiderations.

(a) *Standard reconsideration: Request for services.*

(1) If the M+C organization makes a reconsidered determination that is completely favorable to the enrollee, the M+C organization must issue the determination (and effectuate it in accordance with §422.618(a)) as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration. The M+C organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). When the M+C organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision to grant an extension. For extensions, the M+C organization must issue and effectuate its determination as expeditiously as the enrollee's

health condition requires, but no later than upon expiration of the extension.

* * * * *

(d) *Expedited reconsideration*--* * *

(2) *Extensions*. The M+C organization may extend the 72-hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). When the M+C organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision to grant an extension. The M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension.

(3) *Confirmation of oral notice*. If the M+C organization first notifies an enrollee of a completely favorable expedited reconsideration, it must mail written confirmation to the enrollee within 3 calendar days.

(4) *How the M+C organization must request information from noncontract providers*. If the M+C organization must receive

medical information from noncontract providers, the M+C organization must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited reconsideration. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the M+C organization in meeting the required timeframe. Regardless of whether the M+C organization must request information from noncontract providers, the M+C organization is responsible for meeting the timeframe and notice requirements.

* * * * *

(g) *Who must reconsider an adverse organization determination.* * * *

(2) When the issue is the M+C organization's denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the reconsidered determination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the reconsidered determination need not, in all cases, be of the same specialty or subspecialty as the treating physician.

68. In §422.594, the introductory text for paragraph (b) is republished, and paragraph (b)(1) is revised to read as follows:

§422.594 Notice of reconsidered determination by the independent entity.

* * * * *

(b) *Content of the notice.* The notice must--

(1) State the specific reasons for the entity's decisions in understandable language;

* * * * *

69. Revise §422.596 to read as follows:

§422.596 Effect of a reconsidered determination.

A reconsidered determination is final and binding on all parties unless a party other than the M+C organization files a request for a hearing under the provisions of §422.602, or unless the reconsidered determination is revised under §422.616.

70. Revise §422.612(b) to read as follows:

§422.612 Judicial review.

* * * * *

(b) *Review of Board decision.* Any party, including the M+C organization, may request judicial review (upon notifying the other parties) of the Board decision if it is the final decision of HCFA and the amount in controversy is \$ 1,000 or more.

* * * * *

71. Section 422.618 is amended by:

A. Revising the section heading.

B. Redesignating paragraph (b) as paragraph (c).

C. Adding a new paragraph (b).

D. Revising newly designated paragraph (c).

§422.618 How an M+C organization must effectuate standard reconsidered determinations or decisions.

* * * * *

(b) Reversals by the independent outside entity.

(1) Requests for service. If, on reconsideration of a request for service, the M+C organization's determination is reversed in whole or in part by the independent outside entity, the M+C organization must authorize the service under dispute within 72 hours from the date it receives notice reversing the determination, or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days from that date. The M+C organization must inform the independent outside entity that the organization has effectuated the decision.

(2) Requests for payment. If, on reconsideration of a request for payment, the M+C organization's determination is reversed in whole or in part by the independent outside entity, the M+C organization must pay for the service no later than 30 calendar days from the date it receives notice reversing the organization determination. The M+C organization must inform the

independent outside entity that the organization has effectuated the decision.

(c) *Reversals other than by the M+C organization or the independent outside entity.* If the independent outside entity's determination is reversed in whole or in part by the ALJ, or at a higher level of appeal, the M+C organization must pay for, authorize, or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 calendar days from the date it receives notice reversing the determination. The M+C organization must inform the independent outside entity that the organization has effectuated the decision.

72. Add new §422.619 to read as follows:

§422.619 How an M+C organization must effectuate expedited reconsidered determinations.

(a) *Reversals by the M+C organization.* If on reconsideration of an expedited request for service, the M+C organization completely reverses its organization determination, the M+C organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the M+C organization receives the request for reconsideration (or no

later than upon expiration of an extension described in §422.590(d)(2)).

(b) *Reversals by the independent outside entity.* If the M+C organization's determination is reversed in whole or in part by the independent outside entity, the M+C organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination. The M+C organization must inform the independent outside entity that the organization has effectuated the decision.

(c) *Reversals other than by the M+C organization or the independent outside entity.* If the independent review entity's expedited determination is reversed in whole or in part by the ALJ, or at a higher level of appeal, the M+C organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 days from the date it receives notice reversing the determination. The M+C organization must inform the independent outside entity that the organization has effectuated the decision.

73. Section 422.620 is revised to read as follows:

§422.620 How enrollees of M+C organizations must be notified of noncoverage of inpatient hospital care.

(a) *Enrollee's entitlement.* Where an M+C organization has authorized coverage of the inpatient admission of an enrollee, either directly or by delegation (or the admission constitutes emergency or urgently needed care, as described in §§422.2 and 422.113), written notice of noncoverage under paragraph (c) of this section must be provided to each enrollee. An enrollee is entitled to coverage until at least noon the day after such notice is provided. If PRO review is requested under §422.622, coverage is extended as provided in that section.

(b) *Physician concurrence required.* Before notice of noncoverage is provided as described in paragraph (c) of this section, the entity that makes the noncoverage/discharge determination (that is, the hospital by delegation or the M+C organization) must obtain the concurrence of the physician who is responsible for the enrollee's hospital care.

(c) *Notice to the enrollee.* In all cases in which a determination is made that inpatient hospital care is no longer necessary, no later than the day before hospital coverage ends, written notice must be provided to the enrollee that includes the following elements:

(1) The reason why inpatient hospital care is no longer needed.

(2) The effective date and time of the enrollee's liability for continued inpatient care.

(3) The enrollee's appeal rights.

(4) Additional information specified by HCFA.

74. Revise §422.648(b) to read as follows:

§422.648 Reconsideration: Applicability.

* * * * *

(b) HCFA reconsiders the specified determinations if the contract applicant or the M+C organization files a written request in accordance with §422.650.

75. In §422.650, paragraphs (c) and (d) are revised to read as follows:

§422.650 Request for reconsideration.

* * * * *

(c) *Proper party to file a request.* Only an authorized official of the contract applicant or M+C organization that was the subject of a contract determination may file the request for reconsideration.

(d) *Withdrawal of a request.* The M+C organization or contract applicant who filed the request for a reconsideration may withdraw it at any time before the notice of the reconsidered

determination is mailed. The request for withdrawal must be in writing and filed with HCFA.

76. Revise §422.652 to read as follows:

§422.652 Opportunity to submit evidence.

HCFA provides the M+C organization or contract applicant and the HCFA official or officials who made the contract determination reasonable opportunity, not to exceed the timeframe in which an M+C organization could choose to request a hearing as described at §422.662, to present as evidence any documents or written statements that are relevant and material to the matters at issue.

77. Revise §422.656 to read as follows:

§422.656 Notice of reconsidered determination.

(a) HCFA gives the M+C organization or contract applicant written notice of the reconsidered determination.

(b) The notice--

(1) Contains findings with respect to the contract applicant's qualifications to enter into, or the M+C organization's qualifications to remain under, a contract with HCFA under Part C of title XVIII of the Act;

(2) States the specific reasons for the reconsidered determination; and

(3) Informs the M+C organization or contract applicant of its right to a hearing if it is dissatisfied with the determination.

78. In §422.660, the introductory text is republished and paragraph (a) is revised to read as follows:

§422.660 Right to a hearing.

The following parties are entitled to a hearing:

(a) A contract applicant that has been determined in a reconsidered determination to be unqualified to enter into a contract with HCFA under Part C of title XVIII of the Act.

* * * * *

79. In §422.662, paragraphs (a) and (b) are revised to read as follows:

§422.662 Request for hearing.

(a) *Method and place for filing a request.* A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or M+C organization that was the party to the determination under appeal. The request for a hearing must be filed with any HCFA office.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 days after the date of the reconsidered determination.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773,
Medicare--Hospital Insurance; and Program No. 93.774,
Medicare--Supplementary Medical Insurance Program)

Dated: _____

Nancy-Ann Min DeParle
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Approved: _____

Donna E. Shalala
Secretary.

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